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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,932	11/03/2003	Michael Schink	104035.271139	4940

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,932	SCHINK ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11/3/03;2/2/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' preliminary amendment filed 02/18/2004; IDS filed 11/03/2003; and IDS filed 02/02/2005.

Claims 1-25 are pending and included in the prosecution.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on May 02, 2001. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, and 5-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-7, 12, 19-22, 26-28, 33, 34, 37, and 38 of copending Application No. 10/735,310. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter directed to polyurethane matrix comprising active agent and penetration enhancer in the same amounts and the polyurethane matrix having the same thickness. The difference between the present claims and the copending claims is that the present claims recite the active agent applied to the matrix in a liquid or dissolved form. The method of applying the active agent to the matrix does not impart patentability to claims directed to product since the end product will be polyurethane matrix comprising active agent and permeation enhancer. The present claims directed to matrix, which the generic, and the copending claims recite the species gel matrix. This is an anticipatory type of obviousness double patenting rejection since the copending claims anticipate the present claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2 recites the limitation "solvent" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 6, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, the broad limitation is "pharmaceutically active substances" and the narrow limitations are "essential oils", and "antiseptics".

Furthermore, the expression "cosmetic skin-care additives" in claim 6 does not set forth the metes and bounds of the claim. Recourse to the specification does not define the expression.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 5-8 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 212 681 ('681).

EP '681 disclosed drug releasing system comprised of a drug dispensing polyurethane matrix (abstract). The drug present in amount of 1-10% by weight of the matrix (col.4, lines 50-51). The drug is dissolved in the matrix that further comprises permeation enhancer (col.5, lines 7-12). The matrix is cured, i.e. solvent evaporated (col.5, lines 13-15)

8. Claims 1, 2, 11, 12, 5-8 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,839,174 ('174).

US '174 disclosed transdermal drug delivery system comprising a polyurethane matrix layer containing 5-50% of active agent dispersed in the matrix in a liquid form (abstract; col.2, lines 55-58; col.4, lines 9-10). The matrix is cured, i.e. solvent evaporated (col.3, lines 24-25). After curing the matrix have a thickness range from 50 to 800 micron (col.6, lines 1-5).

9. Claims 1, 3, 6-10, 16-20, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,958,447 ('447).

US '447 disclosed adhesive matrix type transdermal patch and method of its manufacture, wherein the adhesive matrix is loaded with the active substances in a liquid form (abstract; col.2, lines 62-67). The liquid active substance diffuses into the matrix and the matrix remains adhesive over its entire delivery surface that comes in contact the skin (col.3, lines 9-15). The liquid contains 1-33% of active substance and up to 10% of glycerin, ethanol, glycols, mineral oils, and lanoline, which are known to be permeation enhancers (col.11, lines 25-40; col.12, lines 50-62). The transdermal patch is manufactured by depositing the active substance on the adhesive matrix by printing process (col.4, lines 26-41; col.10, lines 53-56). The adhesive matrix can be made of urethanes (col.6, line17).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 3, 4 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US 4,915,950 ('950).

The teachings of EP '681 are discussed under 102 rejection above.

However, EP '681 does not teach the method by which the active agents are applied to the matrix, dexpanthenol as an active agent as claimed in claim 25, or the amount of the enhancer.

The amount of the enhancer does not impart patentability to the claims, absent evidence to the contrary.

US '950 teaches method of making transdermal drug delivery system wherein the active agents are printed or sprayed in the liquid or dissolved form on the drug carrying layer with a key advantage of having uniform deposition of the of the active agent on the surface of the drug carrying layer (abstract; col.2, lines 15-16, 48-56; col.3, lines 25-31).

Applicants did not show superior and unexpected results from using dexpanthenol as an active agent in the process of making the patch.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising polyurethane matrix containing the drug in a liquid form as disclosed by EP '681, and apply the active ingredient to the adhesive matrix by printing or spraying as disclosed by US '950, motivated by the teaching of US '950 that printing or spraying the active agent in the liquid or dissolved form on the drug carrying layer is the key advantage of having uniform deposition of the of the active agent of the surface of the drug carrying layer, with reasonable expectation of having transdermal drug delivery system wherein the drug is uniformly deposited on a polyurethane matrix layer with the consequence of uniform delivery of the active agent.

13. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681 in view of US '6,419,935 ('935).

The teachings of EP '681 are discussed under 102 rejection above.

However, EP '681 does not teach the thickness of the matrix or dexpanthenol and its concentration in the matrix.

US '935 teaches transdermal patch to deliver comprising an adhesive matrix comprising active agents such as panthenol and D-panthenol that has skin beneficial effect (abstract; col.3, lines 15-24; col.5, lines 24, 28, 48). The thickness of the adhesive matrix varies from 5-500 microns depending on the active agent to be delivered (col.6, lines 12-17).

The concentration of the panthenol in the matrix does not impart patentability to the claims, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising polyurethane matrix containing the drug in a liquid form as disclosed by EP '681, and adjust the thickness of the matrix between 5-500 micron and incorporate panthenol as the active ingredient as disclosed by US '935, motivated by the teaching of US '935 that thickness of the matrix varies depending on the active agents and the panthenol has beneficial effect on the skin, with reasonable expectation of having a transdermal patch having an adhesive matrix with thickness between 5-500 micron that delivers panthenol and provides beneficial effect to the skin of the user.

14. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '681.

The teachings of EP '681 are discussed under 102 rejection above.

However, EP '681 does not teach the amount of the permeation enhancer or the thickness of the matrix.

The amount of the enhancer and the thickness of the matrix do not impart patentability to the claims, absent evidence to the contrary.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have an adhesive matrix with a thickness between 10-3000 μm, and adjust the amount of the enhancer according to the specific patient need and the

drug delivered, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

15. Claims 3, 4, 9, 10, and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '174 in view of US 4,915,950 ('950).

The teachings of US '174 are discussed under 102 rejection above.

However, US '174 does not teach the method by which the active agents are applied to the matrix, dexpanthenol as an active agent, or the enhancer and its amount.

US '950 teaches method of making transdermal drug delivery system wherein the drug and a permeation enhancer are printed or sprayed in the liquid or dissolved form on the drug carrying layer with a key advantage of having uniform deposition of the of the active agent of the surface of the drug carrying layer (abstract; col.2, lines 15-16, 48-56; col.3, lines 25-31; col.7, lines 49-50). The enhancer increases the permeability of the drug to the skin of the user (col.7, lines 55-57).

The amount of the enhancer does not impart patentability to the claims, absent evidence to the contrary.

Applicants did not show superior and unexpected results from using dexpanthenol as an active agent in the process of making the patch.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising polyurethane matrix containing the drug in a liquid form as disclosed by US '174, and

apply the active ingredient to the adhesive matrix by printing or spraying with a permeation enhancer as disclosed by US '950, motivated by the teaching of US '950 that printing or spraying the active agent in the liquid or dissolved form on the drug carrying layer the key advantage of having uniform deposition of the of the active agent of the surface of the drug carrying layer, and the permeation enhancer increases the permeability of the drug to the skin of the user, with reasonable expectation of having transdermal drug delivery system wherein the drug is uniformly deposited on a polyurethane matrix layer with the consequence of uniform enhanced delivery of the active agent to the skin of the user.

16. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '174 in view of US '935.

The teachings of US '174 and US '935 are discussed under 102 rejection above.

However, US '174 does not teach dexpanthenol and its concentration in the matrix.

The concentration of the panttenol in the matrix does not impart patentability to the claims, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising polyurethane matrix containing the drug in a liquid form as disclosed by US '174, and adjust the thickness of the matrix between 5-500 micron and incorporate panthenol as the active ingredient as disclosed by US '935, motivated by the teaching of US '935 that

thickness of the matrix varies depending on the active agents and the panthenol has beneficial effect on the skin, with reasonable expectation of having a transdermal patch having an adhesive matrix with thickness between 5-500 micron that delivers panthenol and provides beneficial effect to the skin of the user.

17. Claims 2, 4 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '447 in view of US '950.

The teachings of the reference are discussed above.

US '447 does not teach, evaporation of the solvent, or applying the active agent by spraying process.

Evaporation of the solvent step does not impart patentability to the claims directed to product, absent evidence to the contrary.

US '950 teaches applying active agent into drug carrying layer by spraying the drug in a liquid or dissolved form, and also teaches the equivalency between spraying and printing.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce a transdermal patch comprising self adhesive matrix comprising active agent as disclosed by US '447, and apply the active agent by spraying into the matrix as disclosed by US '950, motivated by the teaching of US '950 that spraying the active agent in the liquid or dissolved form on the drug carrying layer is the key advantage of having uniform deposition of the of the active agent of the surface of the drug carrying layer, with reasonable expectation of having transdermal drug

delivery system wherein the drug is uniformly deposited on the adhesive matrix layer with the consequence of uniform delivery of the active agent.

18. Claims 5, 11, 12, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '447 in view of US 5,844,013 ('013).

The teachings of US '447 are discussed under 102 rejection above.

However, US '447 does not teach the adhesive matrix made of polyurethane as claimed in claims 5 and 22, or the thickness of the matrix layer as claimed in claims 11 and 12.

US '013 teaches polyurethane foam used in medicine and as a wound dressing because it has self adhesive properties on the skin and can be pulled off painlessly from normal skin (abstract; col.18, lines 14-17). The polyurethane foam forms a layer in the wound dressing having a thickness from 10-1000 micron (col.19, lines 55-57).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce a transdermal patch comprising self adhesive matrix made of urethanes and comprising active agent as disclosed by US '447, and replace the urethane with the polyurethane having thickness between 10-1000 micron as disclosed by US '013, motivated by the teaching of US '013 that polyurethane foam of this preferred thickness has self adhesive properties on the skin and can be pulled off painlessly from normal skin, with reasonable expectation of having transdermal patch comprising polyurethane self adhesive matrix delivering active agent to the skin of the patient in need and then is removed painlessly from the skin.

19. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '447 in view of US '935.

The teachings of references are discussed above.

However, US '447 does not teach dexpanthenol and its concentration in the matrix as claimed in claims 13-15.

The concentration of the panthenol in the matrix does not impart patentability to the claims, absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal drug delivery device comprising adhesive matrix containing a drug in a liquid form as disclosed by US '447, and incorporate panthenol as the active ingredient as disclosed by US '935, motivated by the teaching of US '935 that panthenol has beneficial effect on the skin, with reasonable expectation of having a transdermal patch having an adhesive matrix that delivers panthenol and provides beneficial effect to the skin of the user.

Claim Objections

20. Claim 16 is objected to because of the following informalities: the claim has two periods at the end. Appropriate correction is required.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER